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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,640	03/20/2002	Stephen Anthony Burbidge	PG3733USW	5949

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EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	**PAPER NUMBER**
1614	15

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,640	BURBIDGE ET AL.	
	Examin r	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,7 and 9-14* is/are pending in the application.

4a) Of the above claim(s) *3,7 and 9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants Response to Restriction Requirement Acknowledged

1. Acknowledgement is made of Applicants election of the Group III, claim 14, with traverse. Claims 3, 7 and 9-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims, the requirement having been traversed in Paper No. 14.

Claim Objection

2. Claim 14 is objected to because of the following informalities: Misspelling of word "opthalmic" is present in line 6. It should be corrected as "ophthalmic".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 14 is rejected under 35 USC 112, first paragraph, because the specification while being enabling for treating seizure or inflammatory pain, does not reasonably provide enablement for the treatment of "neurotransmission disorders, CNS disorders, functional bowel disorders, neurodegenerative diseases, or tinnitus; preventing or reducing dependence on, or preventing or reducing tolerance or reverse tolerance to, a dependence-inducing agent; the treatment of cancerous disease, inflammatory processes, ophthalmic diseases, cognitive disorders, or migraine; and producing a neuroprotecting, or a centrally acting analgesic effect". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification shows that retigabine opens KCNQ2/3 potassium, apparently through an increase in the kinetics of channel activation in vitro study (page 8, lines 27-28). The specification states that the properties of retigabine on the KCNQ2/3 channel are likely to be a major contributor of its anti-convulsant action in vivo, since KCNQ2 and KCNQ3 are widely and prominently expressed throughout the central nervous system (page 8, lines 29-31). Furthermore, the specification states: "In addition to the anti-convulsant properties of retigabine where the drug protected against pentylene tetrazol-induced seizures in rats...retigabine was also active in the carageenan model of inflammatory pain...Based on this result is extremely likely that an opener of KCNQ2/3 will be active in pain" (page 9, lines 11-21).

It appears in view of the instant specification that applicants claiming for the instant claimed method is entirely based on the activity of retigabine as a KCNQ2/3 potassium channels openers and possible implication of retigabine's KCNQ2/3 potassium channels openers activity on controlling the pathological conditions or diseases states that are mediated through KCNQ/3 potassium channels.

The pharmaceutical art remains highly unpredictable, and no examples exist for efficacy of a single product against all types of claimed conditions or disease generally. The specification fails to provide sufficient guidance or direction whether the disclosed animal model (anti-convulsant activity in rat model and carageenan model of inflammatory pain in rat) could serve as an exemplified animal model for all types of diseases or conditions could be treated by retigabine. Furthermore, the specification fails to provide sufficient guidance or direction whether all types of claimed conditions or diseases are mediated through KCNQ2/3 potassium channels and whether the opening of KCNQ2/3 potassium channel by retigabine could provide

beneficial effects on treating all types of claimed conditions or diseases. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) the quality of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working example,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

As stated above, applicants fails to provide information allowing the skilled artisan to ascertain how to use for the treatment of "neurotransmission disorders, CNS disorders, functional bowel disorders, neurodegenerative diseases, or tinnitus; preventing or reducing dependence on, or preventing or reducing tolerance or reverse tolerance to, a dependence-inducing agent; the treatment of cancerous disease, inflammatory processes, ophthalmic diseases, cognitive disorders, or migraine; and producing a neuroprotecting, or a centrally acting analgesic effect" without undue experimentation. In the instant case, the specification examples are drawn to the activity of retigabine in controlling seizure and pain. It is noted that these examples are neither

exhaustive, nor define the class of diseases required. The instant claims read on all types of disease or conditions, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. In view of the nature of the invention, the state of the prior art, the relative skill of those in the art, the breadth of the claims and the amount of guidance present in the specification, it would take undue trials and errors to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by admitted prior art of the record (page 9, lines 11-20).

Applicants admitted prior art of the record teaches the use of retigabine for treating seizures and inflammatory pain in mammals.

Conclusion

5. No Claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Zohreh Fay